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REBUTTAL TO: "TOBACCO INDUSTRY RESPONSE TO A RISK ASSESSMENT OF ENVIRONMENTAL TOBACCO SMOKE," BY LISA A. BERO AND STANTON A. GLANTZ

In their paper entitled "Tobacco Industry Response to a Risk Assessment of Environmental Tobacco Smoke," Bero and Glantz present an analysis of "tobacco industry responses" to the public comment docket for the U.S. EPA Draft Risk Assessment on environmental tobacco smoke (1990). The comments are catalogued according to subject matter and the type of support derived from the scientific literature. The authors conclude that their analysis shows "the majority of comments that were critical of the Risk Assessment were submitted by tobacco industry-affiliated reviewers. The critical comments differed in content from the Science Advisory Board Report and were supported by more non-peer reviewed references." (p. 2)

Bero and Glantz determine whether individual comments are "tobacco-affiliated" or not in order to test the hypothesis that "comments which oppose the conclusions of the draft Risk Assessment were no more likely to be submitted by individuals affiliated with the tobacco industry than others." (p. 4) This was done because, according to Bero and Glantz, "it is sometimes difficult to determine whether or not an industry's response to a regulatory policy is a valuable scientific contribution to the Risk Assessment or mere advocacy of the industry's economic

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interest" (p. 3), even though the authors later concede that "the strategy of criticizing the methodology of studies that have a potential impact on one's economic or political position is common to all industries." (p. 15, emphasis added) The authors then compare the editorial review policies for references cited in all the comments on the Risk Assessment in order to assess the "scientific rigor" of the citations. (p. 4) The authors contend that the arguments presented by commentators affiliated with "the tobacco industry" differed from those of the Science Advisory Board and "were supported by the selective citation of non-peer reviewed literature." (p. 2)

REPLY:

The Bero-Glantz strategy is an effort to neutralize and discount scientific comments critical of the EPA Draft Risk Assessment on ETS by suggesting that the comments were somehow influenced, financially or otherwise, by the tobacco industry. The authors imply that the critical comments are largely irrelevant because they did not concur with the evaluation of the Risk Assessment by the Science Advisory Board and they were not supported by what Bero and Glantz determine as scientifically rigorous documentation.

- Nowhere in the analysis and discussion proffered by Bero and Glantz are the strengths, weaknesses or specific merits of the

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scientific arguments in the public comments addressed. Nor do the authors attempt to provide the reader with a detailed account of the specific scientific issues and criticisms discussed in the critical comments for the draft Risk Assessment. Such a summary does exist and was alluded to, but not discussed, by Bero and Glantz. It was written by the principal contracting author of the 1990 Draft Risk Assessment and was presented to the Science Advisory Board during their 1990 deliberations. (See: "A Brief Summary of the Public Comments Submitted to the U.S. EPA in Response to the External Review Draft EPA/600/6-90/006A - Health Effects of Passive Smoking: Lung Cancer in Adults and Respiratory Disorders in Children.") The summary presents an objective characterization and evaluation of the arguments critical of the Risk Assessment. Unlike the approach taken by Bero and Glantz, the summary presents a discussion of the merits of the scientific arguments and data presented in the public comments.

- The "revelation" that the majority of comments critical of the Risk Assessment were submitted by scientists at the request of the "tobacco industry" should not be surprising. After all, the tobacco industry is the affected industry regarding ETS. As an affected industry, it has every right to set the scientific record straight and to respond to what is perceived as a campaign of disinformation on ETS. The Bero and Glantz suggestion that a scientist who responds at the behest of an industry somehow has been compromised serves only to disparage the industry and the scientist

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involved, and to divert attention from the scientific merits of the arguments presented in the response. Data and scientific arguments stand or fall on scientific merits only, regardless of the source. Bero and Glantz undoubtedly know this, and, in light of the scientifically devastating comments on the Risk Assessment offered in the public docket, chose instead to attempt to convince the reader that such arguments could be dismissed out of hand, regardless of scientific content.

• Had Bero and Glantz truly intended to provide an objective review of contributors to the public comment docket, they also would have analyzed, according to affiliation, the comments submitted to the public docket which were supportive of the Risk Assessment. Those comments were submitted by representatives of anti-smoking organizations, individuals who have made public anti-smoking pronouncements, representatives of governmental agencies with smoking control agendae and researchers who are beholden to those governmental agencies for grants. Why did these comments not receive scrutiny by Bero and Glantz? Moreover, Bero and Glantz claim that "the majority of respondents who supported the Risk Assessment were not paid for their critiques," while the majority of critical commentors were. This is absurd. It suggests that those with an anti-smoking bent do not have a financial, professional or vested interest in the issue of ETS. What scientist or researcher, other than the independently wealthy, could afford to spend the time needed to carefully read

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the Risk Assessment, review supporting and critical literature, and prepare comments to submit to the public docket? And what would motivate them, given that the issue is of interest essentially only to the tobacco industry and those who are bent on smoking control? It is misleading to suggest that those individuals who submitted comments in favor of the risk assessment were acting simply out of altruism and concern for mankind, and were not "paid" for their time.

- In another attempt to undermine the credibility of the critical arguments against the Risk Assessment, Bero and Glantz compare the patterns of arguments presented by critical commentors with those of the Science Advisory Board. They write: "[O]verall, the SAB was in concordance with 4 out of 50 criticisms presented by TI reviewers and was not in concordance with 27 criticisms made by TI reviewers. The SAB did not mention 19 criticisms made by TI reviewers." (p. 8) Bero and Glantz do not mention that members of the SAB publicly acknowledged that they had not reviewed even selected comments to the public docket. Forty percent of the issues raised in the critical comments were, according to Bero and Glantz, not even mentioned by the SAB.

- Why was there little concordance between the critical reviewers of the Risk Assessment and the SAB report? We know that the SAB members did not review the 107 public comments to the EPA docket. In their defense, each and every member of the SAB holds

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a position which may not permit the use of such time. However, the lack of concordance may also indicate the SAB's lack of understanding of the many issues involved. Bero and Glantz do not address this possibility. Nor do Bero and Glantz explore the issue of possible conflict of interest for the SAB members themselves. One member of the Science Advisory Board panel included a well-known anti-smoking activist and other members of the panel have made public pronouncements against smoking and ETS. Still another member of the SAB panel was part of a research team responsible for one of the largest ETS studies ever conducted. Although the study reported a negative association between the incidence of lung cancer and marriage to a smoker, the SAB member failed to disclose this fact or the results of the study to other SAB members while the 1990 Draft Risk Assessment was under consideration.

Moreover, if one were to play the Bero-Glantz game regarding the identification of possible financial conflicts of interest, most of the SAB panel members are past recipients of research grants from the EPA! The chairman of the panel candidly admitted to the press that "[i]t's not that I'm a tool of the industry. I'm a bigger tool of government. I've been working for the EPA longer. I have more to lose by offending EPA than industry." (Los Angeles Times, November 24, 1990: A-27) Moreover, several of the SAB panel members had reviewed or drafted portions of the Risk Assessment and others were responsible for scientific studies that were discussed and cited in the report. Those

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panelists were thus put in a position of evaluating their own work. In light of this, it may therefore not be surprising that there was a lack of concordance between the SAB report and comments critical of the draft Risk Assessment.

• In a number of places in the article, Bero and Glantz misrepresent the content of various public comments and mislead the reader about various issues discussed therein. For example: Bero and Glantz argue that the litmus test for "scientific rigor" is citation to peer-reviewed scientific literature. (pp. 2, 4, 15) While important, the peer review process is not infallible and it does not guarantee either the veracity or the integrity of research. It is also a process which is not itself devoid of potential bias or subjectivity. Any scientist who has attempted to publish a study outside "mainstream" thinking or which reports a negative association is likely to have experienced a peer-review "bias." This is particularly true with regard to papers on smoking and ETS. Moreover, letters to the editor, symposia reports and other examples of non peer-reviewed literature contain valuable information and they frequently provide authors with an alternative forum to present research, new data and interpretation. The content of the message, contrary to Bero and Glantz, is what is at issue here. Scientific truth deals with content and data and not with the vehicle of presentation.

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• Bias on the issue of ETS is exhibited by Bero and Glantz in a number of statements found in their paper. For example, in their abstract they state that the arguments presented by commentors critical of the Risk Assessment were supported "by the selective citation of non-peer reviewed literature," and that the EPA "cited more references on ETS (32% versus 15%) and fewer non-refereed publications (27% versus 37%)." (p. 2) The data presented in Bero and Glantz's paper do not support those claims. For example, the absolute number of "non-peer reviewed" references cited in critical comments was 602 versus 105 cited in the draft Risk Assessment, while comments critical of the Risk Assessment cited 1,018 peer-reviewed reference versus the EPA's 286! (Table 3) Elsewhere, Bero and Glantz admit "overall, submissions critical of the Risk Assessment cited 4 times as many individual references (and equals 1620) as the draft Risk Assessment (and equals 391)." Nowhere in the paper or the accompanying tables are the claims regarding "selective citation of non-peer reviewed literature" supported. Nor are any absolute numbers given for the claim that "the EPA cited more references on ETS." Thus, the suggestion claim that "the proportion of peer reviewed materials cited by the EPA differed from that cited by critical reviewers (73% versus 63%) (Table 3)" (p. 15) is misleading and would have read differently had absolute numbers of comments been considered, i.e., critical comments cited 1,018 peer-reviewed articles versus the EPA's 286. (Table 3)

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• Bero and Glantz state that "tobacco industry affiliated reviewers sometimes misrepresented the findings of individual studies. Several reviewers claimed the EPA failed to consider a doctoral dissertation that found no effect of passive smoking on nonsmokers. When the dissertation data were published in peer reviewed literature, the data actually showed a moderate association of ETS and lung cancer." (pp. 16-17) Actually, the dissertation referred to by Bero and Glantz was the largest case-control study conducted to date in the United States. Contrary to Bero and Glantz, only a portion of the dissertation data was published in the peer-reviewed literature and all of the major conclusions of the dissertation stood, namely, no association between spousal smoking and lung cancer in female nonsmokers, no association from exposure in the workplace and no association from exposure in social settings. One subset analysis in the paper appeared to suggest an increased risk of lung cancer in adults who were heavily exposed to ETS during childhood, but the data were so anomalous that the authors themselves "were unable to explain" the reported finding.

• Bero and Glantz also suggest that "although most of the literature cited to support the argument on confounders was peer reviewed [in criticisms of the draft Risk Assessment], the papers did not include a direct comparison of health effects associated with ETS exposure and other factors." (p. 17) Yet the Philip Morris submission alone to the public docket contained a discussion of 17 references, 14 of which were peer-reviewed and all available to

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the EPA, which addressed the issue of confounders and the direct comparison of confounding for health effects reportedly associated with ETS and other factors. (See Comments of Philip Morris, Inc., September 28, 1990, pp. 87-96)

- A number of comments in the Bero-Glantz paper also indicate the authors lack of sensitivity to the issues involved in the scientific debate on ETS. They discount criticism "levied by 36 TI reviewers . . . that the draft failed to adequately consider potential confounding variables . . ." by citing the SAB report in which it is suggested that "there is no way to evaluate" or "adjust" for confounding variables, "since virtually none of the studies contain information on them." (p. 12) The point of the critical comments was that one had to look to the scientific literature outside the studies themselves for information and data on potential confounders. Bero and Glantz, as well as the SAB, completely missed this point.

- The authors also state that "after considering the limitations of ETS exposure measurements, the SAB concluded that ETS exposure can be estimated and that 'spousal smoking status seems to be a reasonable method of identifying people with greater, versus lesser, ETS exposure.'" (p. 13) Bero and Glantz fail to mention that the draft Risk Assessment did not include either an exposure assessment or a review of over 100 available studies on ETS exposures in the literature. They do not discuss the fallibility

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of estimating exposure via questionnaire response rather than through actual exposure data. The SAB's point that spousal smoking status is a reasonable method of identifying people with "greater versus lesser ETS exposure" does not address the issue of how much exposure a nonsmoker encounters. Indeed, one SAB panel which reviewed the literature on diesel exhaust refused to accept epidemiologic estimates of exposure for just that reason -- such estimates are not quantitative.

- Bero and Glantz state that "seven TI reviewers argued that the EPA did not follow its own Risk Assessment guidelines. The SAB stated that the Risk Assessment guidelines, which were designed to address a single chemical compound, were not directly applicable to ETS." (p. 14) The point of the critical reviewers was that, given the four components of risk assessment established in the EPA's own guidelines for carcinogens, the draft Risk Assessment failed to provide an exposure assessment, an adequate hazard identification, an appropriate dose-response evaluation and did not include a discussion of uncertainty parameters for its risk characterization on ETS. The SAB, in their report, exhibited their own bias on the issue by claiming that if the Risk Assessment guidelines could be used to show that ETS is not a carcinogen, then the guidelines should be changed! Of course, the SAB report again misses the point of the issue, namely, that the data and evidence proffered by the EPA failed to meet the standards set

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forth by EPA's own guidelines and therefore do not support the EPA's designation of ETS as a Group A carcinogen.

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